IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Michel H. Klein
Appl'n. No.	:	09/479,240
Filed	:	January 7, 2000
Title	:	CHIMERIC IMMUNOGENS
Grp./A.U.	:	1645
Examiner	:	Albert Mark Navarro
Docket No.	:	1038-1000 MIS:jb
Date	:	October 22, 2003

PETITION TO THE DIRECTOR UNDER 37 CFR 1.181

BY COURIER

Mail Stop Petition
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
U.S.A.

Dear Sir:

1. Petition and Statement of Facts

In response to the Examiner's communication of September 23, 2003, Petition is hereby made under the provisions of 37 CFR 1.181 with respect to the Examiner's objection to the Amendment of January 7, 2000 under 35 USC132 on the basis that the Amendment introduces new matter into the disclosure. Our cheque in the amount of the Petition fee is enclosed.

The Examiner first identified the new matter in an Office Action dated February 21, 2002, as Amendment to the sequence of Figure 5 to recite a new nucleotide at positions 540 and 630 and to the resulting amino acid at the position corresponding to site 630 of the nucleic acid sequence. The Examiner is correct that these changes are those sought to be made. The Examiner considered each of the changes to constitute new matter. The position was reported in the Office Action of September 9, 2002 and in an Advisory Action dated September 29, 2003. It is the

applicants position that the changes correct clerical errors and do not involve new matter. The respective positions are discussed below under the heading "Argument".

It was the applicants view that, since the basis of the objection was statutory in nature, namely 35 USC 132, the matter was appealable to the Board of Appeals and submitted a Notice of Appeal and an Appeal Brief.

The Examiner took the view that the objection was not appealable and communicated his position in the communication of September 23, 2003, but permitted a one-month term for submission of this Petition. This Petition ensued.

2. Point to be Reviewed and Action Requested

The point to be reviewed is whether or not applicants Amendments made to Figure 5, specifically Figure 5B, constitute prohibited added subject matter contrary to 35 USC 132 or constitute permitted correction of clerical errors. Applicants hereby request that the Examiner's objection be set aside and the application be permitted to proceed to allowance with the corrections made to Figure 5B. (All claims currently stand allowed).

3. Argument

Figures 5A to 5E show the nucleotide sequences and deduced amino acid sequences for the respiratory syncytial virus fusion (RSV F) protein. Shortly after the grand-parent application was filed, it was discovered that, in preparing the Figure, certain nucleotides, at positions 540 and 630, were transcribed in error. A Preliminary Amendment was submitted with this application to correct the errors in Figure 5B.

The change of "T" to "C" at position 540 leads to a change of the complementary nucleotide from "A" to "G". The change of "G" to "A" at position 630 leads to a change in the complementary nucleotide "C" to "T". This change also leads to a change of the amino acid encoded by the codon including position 630 from "ARG" to "GLN".

Thus, applicants seek to change the identification of two nucleotides, the other changes being consequential on the change of identification of the two nucleotides.

The errors are clerical in nature, arising from transcription of the sequences for inclusion in the grand-parent application. It has always been possible to correct clerical errors in patent specifications and, indeed, Examiner's habitually ask applicants to check their specification in order to detect and correct clerical errors. No one derives any benefit from an erroneous specification, neither applicants nor the public. As noted above, the Examiner characterizes the changes that applicant has made as new matter.

The corrections sought to be made to the sequences are quite different from those decided as new matter in the *Ex parte Maizel*, 27 USPQ2d p1664 and are akin to the changes permitted in *Ex parte Marsili*, 214 USPQ p.904. A copy of each of these decisions is enclosed for convenience.

In *Ex parte Maizel*, the errors sought to be corrected arose in the original sequencing of the DNA coding sequence, which came to light upon resequencing. The original sequencing contained errors which lead to frame shifting and an erroneous encoded amino acid sequence. By way of contrast, applicants had already expressed the RSV F gene and, indeed, correctly presented the sequence in the priority GB 9200117.1. A copy of that GB specification is of record, but is enclosed for convenience.

It is clear that the corrections are minor, being two in number and giving rise to only a single amino acid change. The single amino acid difference is unlikely to have any affect on the functionality of the protein. As applicants state in the specification, the nucleotide sequence encoding the RSV F given in Figures 5A to 5D differs by approximately 1.8% divergence in the coding sequences, resulting in eleven amino acid substitutions (square boxes in Figures 5A to 5E; page 15, lines 15 to 18), from a published sequence of the RSV F gene.

As mentioned above, the applicants were already in possession of the DNA encoding the RSV F protein at the time of filing of their priority GB 9200117.1. The nucleotide and amino acid sequences are set forth in the priority application in Figure 5 and a restriction map of the gene is shown in Figure 6 of the priority application. The same comparison analysis as is set forth in this application is set forth therein (see page 4, lines 32 to 35 and Figure 5). Figure 5 in the GB application correctly shows the sequence sought to be corrected by the Amendments made.

A scientific paper was published in the August 12, 1994 edition of Biotechnology, after the effective filing date of this application, describing the scientific work which is the basis for the patent application. A copy of the scientific paper is of record herein, but is attached for convenience. In connection with that scientific paper, there was submitted to GenBank on September 23, 1993, after the effective filing date of this application, the nucleic acid and encoded amino acid sequences for the RSV F protein. A copy of the GenBank deposit is of record, but a further copy is enclosed for convenience.

The sequences shown in the GenBank deposit are the same as those filed with the priority GB application and do not contain the errors present in Figure 5B and sought to be corrected. It is submitted that the sequences that form part of the GB application and the GenBank deposit constitute collateral evidence that the changes are corrections of errors. In the Advisory Action dated July 29, 2003, the Examiner comments that:

> "Applicants could just as easily discovered a sequence error in the foreign priority document and corrected them for filing of the US application."

This scenario is highly unlikely, since the GenBank deposit, made after this filing, contains the same sequences as the foreign priority document and applicant is seeking to correct the sequence presented in this application.

In addition, the specification describes the preparation of plasmid pD2RF-HN in Example 9 of the specification. Such plasmid was deposited with

ATCC on December 17, 1992, before the effective filing date of this application, under accession number 75388 (see page 12, lines 27 to 43).

As described in Example 9, the RSV F gene lacking the transmembrane domain and cytoplasmic tail was linked to the PIV-3 HN gene devoid of the hydrophobic anchor domain and cloned into baculovirus expression vector pD2 to provide plasmid pD2 RF-HN. As is seen from Figure 5, the portion of the RSV F nucleotide sequence that is present in the deposited plasmid encompasses that where the corrections are sought to be made. A person sequencing the RSV F gene from plasmid pD2 RF-HN would discover the errors in the sequences shown in Figure 5B.

As determined by the Federal Circuit in the *Enzo Biochem Inc. v. Gen-Probe Incorporated et al* [63 USPQ2d p1609], a deposit of a biological material constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of 35 USC 112, first paragraph. A copy of the Decision is enclosed for convenience. Accordingly, the specification as filed contains a written description of the portion of the sequence that is sought to be corrected.

The Examiner relies solely on MPEP 608 for his objection, quoting:

> "All amendments or claims must find descriptive basis in the original disclosure, or they involve new matter."

It is submitted that this statement is not intended to deal with corrections of all types, since corrections are routinely permitted by the Office.

Ex parte Maizel recognizes this principle:

> "We recognize that errors may well arise in the sequencing of DNA and that a mechanism for correcting such errors in the Patent and Trademark Office is highly desirable"

If such errors could not be corrected because of MPEP 608, then there would be no need for the Board to express a desire for a mechanism of correction.

The Board goes on to state:

> "Unfortunately, no general rule can be established because the question of whether or not a change in the chemical structure of a DNA sequence set forth in the specification is permitted depends on the facts of each case and the significance of the modification to both the subject matter *claimed*, i.e., the *invention*, and the subject matter *described* in the specification." (emphasis in original)

Thus, the Board indicated there could be no general rule, but did recognize that a change to a DNA sequence may be permitted, depending on the facts of the situation and the significance of the modification. The Board certainly did not consider that such changes to correct errors were proscribed by MPEP 608.

The facts surrounding the Examiner's rejection are quite different from that in *Ex parte Maizel*. In *Maizel*, the error arose in the sequencing itself, only discovered on resequencing. In this case, the sequencing had been done, as evident from the priority GB application, and the error later arose in transcribing the sequence for the grand-parent application.

In *Ex parte Marsili*, the applicants were permitted to change the chemical structure of a compound as set forth in claim 1 thereof. A more refined investigation of the structure of the compound showed that a hetrocyclic ring, depicted as saturated, was unsaturated at two locations in the ring. This correction was permitted.

4. Summary

Having regard to the contents of this Petition and the argument presented, it is submitted that the Examiner is in error in objecting to the

specification under 35 USC 132 as containing new matter and that the requested changes in Figure 5B should be permitted.

Respectfully submitted,

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PTO/SB/21 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/479,240
Filing Date	January 7, 2000
First Named Inventor	Michel H. Klein
Art Unit	1645
Examiner Name	Albert Mark MNavarro
Total Number of Pages in This Submission	9
Attorney Docket Number	1038-1000 MIS:jb

ENCLOSURES *(check all that apply)*

- [X] Fee Transmittal Form
- [X] Fee Attached
- [ ] Amendment / Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [X] Petition
- [ ] Petition to Convert a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) *(please identify below)*:

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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Michael I. Stewart (Reg. No. 24,973)
Signature	
Date	October 22, 2003

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) **$130.00**

Complete if Known

Application Number	09/479,240
Filing Date	January 7, 2000
First Named Inventor	Michel H. Klein
Examiner Name	Albert Mark Navarro
Art Unit	1645
Attorney Docket No.	1038-1000 MIS:jb

METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number: 192253

Deposit Account Name: Sim & McBurney

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☐ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND

	Extra Claims			Fee from below	Fee Paid
Total Claims		-20** =	0	X =	0.00
Independent Claims		- 3** =	0	X =	0.00
Multiple Dependent				=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) **$0.00**

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130.00
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) **$130.00**

SUBMITTED BY

Name (Print/Type)	Michael I. Stewart	Registration No. (Attorney/Agent)	24,973	Telephone	(416) 595-1155
Signature				Date	October 22, 2003

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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